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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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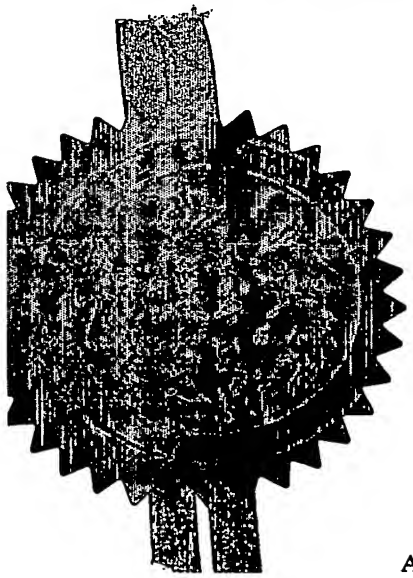

Signed Andrew Gerrard

Dated 10 October 2003

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P01/7700 0.00-0222559.7

THE PATENT OFFICE
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28 SEP 2002
NEWPORT

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
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1. Your reference — ARB/P/203/GBA

2. Patent application number *(The Patent Office will fill in this part)* — 0222559.7 — 28 SEP 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

   CST Medical Limited
   Block B, First Floor
   Shipley Wharfe, Wharfe Street
   Shipley
   West Yorkshire, BD17 7DW
   GB

   Patents ADP number *(if you know it)*

   If the applicant is a corporate body, give the country/state of its incorporation — 08443314 0001

4. Title of the invention — Device

5. Name of your agent *(if you have one)*

   "Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

   BREWSTER, Andrea Ruth et al

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   Cheddar
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   BS27 3EB

   Patents ADP number *(if you know it)*

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

   a) any applicant named in part 3 is not an inventor, or
   b) there is an inventor who is not named as an applicant, or
   c) any named applicant is a corporate body.
   See note (d))

   Yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	12
Claim *(s)*	0
Abstract	0
Drawing *(s)*	4

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Greaves Brewster Date 27-9-02

12. Name and daytime telephone number of person to contact in the United Kingdom: Andrea Brewster 01934 844419

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Notes

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Device

The present invention relates to a device for use in applying a tactile stimulus, in particular to the body.

The device may for instance be used to stimulate sensitive tissue areas such as erectile tissue and in particular the clitoris, and hence is especially suitable for use in the treatment of the syndrome known as female sexual arousal disorder (FSAD).

WO-02/39945 describes an applicator/stimulator device which may be used in the treatment of FSAD, and which facilitates the manual application, to the genital area, of a tactile stimulus together with a lubricant fluid and/or a pharmaceutically active substance such as a vasodilator. The device of WO-02/39945 takes the form of a flexible finger sleeve having one or more fluid-containing cells and preferably also projections to provide additional tactile stimulation. The fluid cell(s) are preferably sealed before use, but rupture under pressure to release the fluid.

The present invention provides alternative forms of such a finger-worn device, which again may be used to apply a tactile stimulus and optionally also to deliver fluid(s) and/or other substance(s) to the stimulated area.

According to a first aspect of the present invention there is provided a device of use in applying a tactile stimulus, the device comprising a sleeve adapted to accommodate a finger, and one or more raised elements on the outer surface of the sleeve, the device being further characterised by one or more of the following features :

a) there is a plurality of raised elements arranged on the outer sleeve surface in the shape of an ellipse or circle.

b) there is at least one raised element, preferably more than one, most preferably 2 or 3 or more, in that region of the sleeve defined by the first 15 %, preferably the first 10 %, of the overall sleeve length measured from the distal end of the sleeve.

c) the raised element(s) are of a greater rigidity than the main body of the sleeve, and are preferably solid.

d) one or more of the raised element(s) at least partly defines a fluid retaining region on the outer sleeve surface.

e) at least one region of the sleeve has a greater flexibility than that of the rest of the sleeve, preferably so as to provide variability in the size (in particular the circumference) of the sleeve.

f) the sleeve has a tearable portion defined at least partly by a region of reduced sleeve strength.

g) the sleeve is provided with a vent to facilitate the release of air from within the sleeve during fitting.

The device preferably incorporates more than one, more preferably two or more and ideally all, of these features.

In this specification, the terms "distal end" and "proximal end" refer to the in-use device, the distal end thus being that which in use will house the free end of the wearer's finger. The word "finger" is intended also to include a thumb.

Such a device allows the manual application of a tactile stimulus and can be, as described above, of particular use in the treatment of FSAD. It will typically be designed for a single use and to be disposable after use.

The sleeve which forms the basis of the device is preferably at least partly, more preferably wholly, made from a flexible and/or elastic material such as a natural or synthetic rubber or plastics material. Suitable materials include polyurethane, polypropylene, silicon and thermoplastic elastomers, preferably the latter. A suitable hardness for this material is Shore A, for instance from 25 to 60°, more typically from 30 to 45°, such as about 40°. Because of its intended use, the sleeve is preferably made from a non-toxic, more preferably pharmaceutical grade, material.

The sleeve may for instance be of the general form described in WO-02/39945. Preferably it will be closed at its distal end, and it will typically have an approximately circular transverse cross section.

Plastics or rubber sleeves may be produced for instance by injection or dip moulding or by injection blow moulding or by casting. Such processes may also be used to achieve the desired profiling of the sleeve surface (including the provision of raised element(s) and if desired indented fluid cells as described below).

The size and shape of the sleeve may depend on those of the finger it is intended to accommodate. A typical length, for instance for a European or North American user, might be from 40 to 80 mm, more suitably from 45 to 75 mm. Its length may vary around its circumference, being for example longer at that face corresponding in use to the upper side of the wearer's finger – at its longest the sleeve might suitably be from 60 to 85 mm, preferably from 65 to 80 mm or from 70 to 75 mm in length, and at its shortest (corresponding typically to the underside of the wearer's finger) from 35 to 60 mm, preferably from 40 to 55 mm, more preferably from 45 to 55 mm in length.

A suitable sleeve circumference may be from 40 to 70 mm or from 45 to 55 mm. Again, the circumference may vary along the sleeve length, being suitably greater (for instance from 50 to 65 mm, preferably from 55 to 60 mm) at the position corresponding to the wearer's proximal finger joint and smaller (for instance from 40 to 55 mm, preferably from 45 to 53 mm) at the distal joint position.

Such dimensions relate to the sleeve in its unflexed state, ie, prior to use on a wearer's finger. Smaller dimensions may be appropriate for instance for South East Asian and other user groups.

The sleeve may be constructed to allow variability in size, for instance as described below in connection with feature (e). It may be capable of accommodating more than one finger. It may be shaped at its distal end to accommodate a finger nail, or otherwise profiled to increase the wearer's comfort, to improve fit and/or to enhance its aesthetic appearance.

The raised element(s) of the device help to provide tactile stimulation during use. By "raised element" is meant an element which protrudes above the outer surface of the sleeve, typically in a direction substantially perpendicular to that of the longitudinal axis of the sleeve.

The number, size, shape and location of the raised element(s) will depend on the intended use of the device, for instance the nature and degree of stimulation it is intended to provide and the aesthetic qualities required of it. Typically there will be more than two raised elements, preferably six or more, more preferably from six to ten, most preferably eight. They are conveniently located at or near the distal end of the sleeve.

The sleeve preferably carries a plurality of raised elements arranged in a closed loop, more preferably (in accordance with feature (a) above) in the shape of an ellipse or circle as opposed to in a linear or angular (eg, rectangular) array. This can help provide the advantages discussed below in connection with feature (d). The diameter of this loop may typically range from 10 to 30 mm, more suitably from 15 to 30 mm.

The raised element(s) are preferably located in a specific region of the device which corresponds, in use, to the underside of the wearer's finger end and which will therefore provide the primary region of tactile stimulation. This "finger tip" region, typically bounded by the wearer's distal finger joint, generally represents the most sensitive and controllable area of the finger. Ideally, according to feature (b) above, at least one raised

element is located in that region of the sleeve surface defined by the first 15 %, preferably the first 10 %, of the overall sleeve length measured from its distal end. Again, such measurements refer to the sleeve in its unflexed state.

Preferably more than one, most preferably 2 or 3 or more raised elements are located in this end region of the sleeve. However, it may be preferable for there to be no raised elements at the very end of the sleeve, in particular none which extends beyond the distal end in the direction generally parallel to that of the longitudinal sleeve axis.

Ideally all, or most (for instance, 70 or 80 % or more), of the raised elements are located in the above described "finger tip" region, typically within that region of the sleeve surface defined by the first 50 %, more preferably the first 40 %, of the overall sleeve length measured from its distal end.

A preferred form of raised element takes the form of a dome-like projection or nodule, of approximately spherical shape or being at least hemispherical at its free end. Its height, above the sleeve surface, may be from 3 to 6 mm, preferably from 4.5 to 5 mm. Its diameter, at the sleeve surface, may be from 3 to 5 mm, preferably from 4 to 4.5 mm.

Where there are two or more raised elements, they may all have the same size and shape or they may differ, and they may be equally or unequally spaced. A typical spacing between raised elements might be from 2 to 6 mm or from 2 to 5.5 mm.

The raised elements are conveniently formed as part of the sleeve wall, for instance during the moulding of the sleeve. Alternatively they may be produced separately and secured to the outer sleeve surface, for example by means of an adhesive, by welding or via a secondary substrate which carries the raised element(s) and is itself then secured to the sleeve surface.

It may be preferable, according to feature (c) above, for the raised element(s) to have a greater rigidity than the main body of the sleeve, to aid the provision of tactile stimulation. This may for example be achieved, if the raised element(s) are to be formed

in the sleeve wall, by increasing the thickness of the sleeve at the raised element(s), or more preferably by moulding the raised element(s) as solid or substantially solid (as opposed to hollow) elements.According to feature (d) above, the raised element(s) may not only provide tactile stimulation but also serve to define a trap which, when the device is used to apply a substance such as a lubricant fluid or a pharmaceutically active substance, helps to retain that substance in the region to which it is intended to be applied, thus reducing wastage and loss. By "fluid retaining region" is meant a region in which a quantity of fluid, such as a lubricant or an active substance-containing fluid, may be at least partially trapped. This region should be defined at least partly by the raised element(s) on the sleeve, and preferably takes the form of an open-topped enclosure bound by the raised element(s) and the outer sleeve surface.

A preferred arrangement of raised element(s) is therefore one which encircles the fluid retaining region, for instance in the approximate shape of an ellipse or circle. Thus ideally either the raised elements are close enough together to inhibit the escape of fluid from the region they encircle, or there are secondary raised elements (typically protruding less far above the sleeve surface) positioned between primary raised elements so that the primary and secondary elements together define a continuous fluid retaining wall. The height of such secondary raised elements, above the sleeve surface, might suitably be from 1 to 2 mm, such as from 1.2 to 1.5 mm.

In a device according to the invention which incorporates feature (e) above, one region of the sleeve should have a greater flexibility than that of the main body of the sleeve. This allows some variability in the sleeve size and hence in the size of finger which it can comfortably accommodate. The higher flexibility region is preferably more stretchable than the main sleeve body when placed on a user's finger, and preferably thereby allows an increase in the sleeve circumference.

The higher flexibility region is typically formed from a higher flexibility material than that of the surrounding sleeve body. Conveniently the higher flexibility region is formed from the same material as that of the rest of the sleeve, but with a lower thickness – this may be achieved by injection moulding for instance. In this case the higher flexibility

region might typically have a thickness of from 15 to 40 % of that of adjacent sleeve regions.

The higher flexibility region may instead be formed from a different material altogether to that of the main sleeve body. It may be formed from a corrugated, crimped or otherwise profiled material which is more able to stretch than the main sleeve body. The material of the higher flexibility region may be perforated (for example, provided with elongate cuts) to facilitate its expansion under strain – such perforations may be incorporated for example during moulding, or subsequently for example by stamping.

As a yet further alternative, the higher flexibility region may be provided in the form of a hole or other break in the sleeve body, optionally bounded by for instance a circumferentially extending strap of a flexible material.Preferably the higher flexibility region is provided at or near the side of the wearer's finger when in use. More preferably, it has an elongate shape orientated substantially in the direction of the finger. It may for instance extend from the proximal end of the sleeve but may terminate short of the distal sleeve end. Its length may be from 50 to 90 %, more preferably from 60 to 80 %, of that of the overall sleeve.

The circumferential (with respect to the overall sleeve) width of the higher flexibility region may be from 5 to 50 % of the sleeve circumference at the relevant point along the sleeve, preferably from 5 to 30 %, more preferably from 8 to 25 %. This width may vary along the length of the higher flexibility region, for example being from 20 to 50 % (or even up to 80 %) of the sleeve circumference at the proximal end of the sleeve but narrower towards the distal end.

The device may comprise two or more higher flexibility sleeve regions at appropriate locations, for instance spaced radially around the sleeve. This can further improve its size variability. Most preferably, there are two higher flexibility regions, ideally one corresponding to each side of the wearer's finger in use.

To facilitate its removal after use, the device of the invention may comprise a tearable portion which may be torn away, either partially or completely, from the rest of the sleeve. According to feature (f) above, this portion may be defined at least partly by a region of reduced sleeve strength, along which the sleeve will tear on application of an appropriate force. The region of reduced sleeve strength may be formed by a boundary between two sleeve regions of differing flexibility, thickness and/or strength.

In a particularly preferred embodiment, the tearable sleeve portion is formed as a higher strength (typically, higher thickness) region of the sleeve between two lower strength (typically lower thickness) regions, its "tear-line(s)" representing the boundaries between regions of differing strengths.

Alternatively the reduced strength region may take the form of scoring or perforations in the sleeve, or of a region formed from a reduced strength (conveniently, reduced thickness) material adjacent the tearable sleeve portion.

Where the device of the invention is provided with a vent, according to feature (g) above, this may for example take the form of an aperture in the sleeve, conveniently at or towards its distal end. Alternatively the sleeve wall may incorporate a channel through which air may be vented during fitting onto a wearer's finger. A vent is of particular value if the sleeve is closed at its distal end.

A vent may be incorporated either during production of the sleeve, for instance by moulding, or subsequently for instance by machining.

The device of the invention may be used to apply substances to an area of stimulation, typical examples being lubricants and pharmaceutically active substances, in particular those which may be of use in the treatment of FSAD such as vasoactive compounds (eg, vasodilators), nerve stimulants and anti-irritants. Thus, the device may be for use as an applicator as well as a stimulator.

In its simplest mode of use, the desired substance is applied to the device from an external source, before the device is brought into contact with the treatment area.

However, the device may itself be adapted to deliver a desired substance. It may for instance incorporate one or more cells which contain the substance and which are adapted to release it during use – typical examples are the fluid-containing cells described in WO-02/39945 in which a fluid is retained by a seal which is preferably openable or rupturable when pressure is applied across it and/or when the seal is in contact with an environment (for instance, a particular temperature or pH) which weakens it. Such cells are ideally defined in the sleeve wall, for instance as indentations, again as described in WO-02/39945, and are preferably located with or in the immediate vicinity of the raised element(s) which provide the tactile stimulation. One or more of the raised elements may also function as a fluid-releasing cell.

The substance may be contained in such cells in any appropriate form such as a solution, suspension, cream, paste or gel.

Generally a device according to the invention may be used to apply a tactile stimulus (optionally together with a substance such as a lubricant) to any area of a patient's body in need thereof, and hence to treat any condition which requires for its alleviation or cure the application of such a tactile stimulus to a part of the body. The device may also be used for non-therapeutic, eg, cosmetic, purposes, including for instance to apply tactile pressure to any surface not necessarily on a living body.

A second aspect of the present invention provides the use of a device according to the first aspect, to apply tactile stimulation for instance to the body, and/or to apply a substance, in particular a fluid, to a surface in particular to living tissue.

The present invention also provides the use of a device according to the first aspect, in the treatment of female sexual arousal disorder (FSAD) or a related condition. It further provides a method of treating FSAD or a related condition, which comprises applying a tactile stimulus to the genital area of a patient using a device according to the first aspect

of the invention, and optionally also applying, using the device, a lubricant and/or an active substance to the stimulated area.

Still further the invention provides a device according to the first aspect, for use in the treatment of a medical condition, in particular FSAD or a related condition.

The present invention will now be described by way of example only and with reference to the accompanying illustrative drawings, of which:

Fig 1 is a perspective view of a device according to the invention, from one side;

Fig 2 is a perspective view of the Fig 1 device, seen from the other side;

Fig 3 is a section taken along the line III-III in Fig 1;

Fig 4 is a section taken along the line IV-IV in Fig 1;

Fig 5 is a section taken along the line V-V in Figs 1 and 2; and

Fig 6 is a perspective view of an alternative device according to the invention.

All figures are schematic.

Referring firstly to Fig 1, the stimulator device shown comprises a finger-shaped sleeve 1 made from a resilient injection moulded thermoplastic elastomer (hardness 40° Shore A). Its dimensions are such as to accommodate a typical human middle finger.

The sleeve has a closed distal end generally labelled 2, close to which are provided a series of eight projections 3. These projections are approximately hemispherical at their free ends. They are formed during the moulding process and are solid, as can be seen in Fig 3, which imparts greater rigidity and enhances the tactile stimulation they provide.

It can be seen from Figs 1 and 4 that between each pair of projections 3 there is a secondary raised portion 4, also formed during injection moulding. The projections and the secondary portions 4 together define a continuous approximately oval wall which acts as a fluid trap labelled 5 in Fig 1. Thus if the device is used with, or more specifically used to apply, a fluid such as a lubricant, at least some of the fluid is likely to be retained in the desired area of application, ie, in the region of the projections 3 which provide the tactile stimulation.

In an alternative version of the Fig 1 device, the projections 3 may be filled with a substance, ideally in fluid form, which is to be applied during use. In this case, to allow release of the fluid at the appropriate time, the outer walls of the projections may be made from a material (for instance, a thin polyurethane) which is rupturable under pressure, or the projections may be open-ended and covered with a subsequently rupturable seal to contain the fluid within them.

Instead or in addition, the device may be provided with one or more fluid-containing cells separate from the projections 3.

Fig 2 shows that side of the device which in use will correspond to the upper side (back) of the wearer's finger. Two elongate panels 10 can be seen which are formed from a thinner polyurethane than that of the rest of the sleeve and whose positions correspond roughly to the sides of the wearer's finger. The reduced thickness panels 10 flank a tear-away panel 11, which has the form of a readily graspable tab.

Following use of the device, the wearer can pull the panel 11 backwards (ie, generally towards the finger ends) to cause it to tear away from the rest of the sleeve along the boundary line 12 between the different thickness panels. This facilitates removal of the sleeve, and also encourages its disposal after use, as might in the context be appropriate.

Panels 10 and 11 can be formed, each to its desired thickness, during injection moulding of the sleeve 1. In the device of Figs 1 to 5, for example, the main body of the sleeve and

the tear-away panel 11 might have a thickness of around 1 mm, whereas the side panels 11 might be between 0.2 and 0.4 mm thick.

In the device of Figs 1 to 5, the height of the projections 3 above the sleeve 1 (measured from the centre of the projection area) might typically be 4.81 mm, that of the intermediate raised portions 4 approximately 1.4 mm. The diameter of the projections (measured at their base, ie, at the sleeve surface) might typically be 4.2 mm. The oval defined by the eight projections might have an approximate length of 28 mm and width of 15 mm.

The length of the sleeve 1 conveniently ranges from approximately 72.5 mm (at the upper face seen in Fig 1) to approximately 49 mm (at the underside face seen in Fig 2). Its circumference is suitably about 49 mm at the position corresponding to the wearer's distal finger joint and about 58 mm at the position corresponding to the proximal joint. The sleeve dimensions may however vary depending on the group of users for which it is intended.

The alternative device shown in Fig 6 is essentially the same as that of Figs 1 to 5 and like parts carry the same reference numerals. The Fig 6 device however is provided, at its distal end, with a vent hole 20 to ease its fitting onto a user's finger.

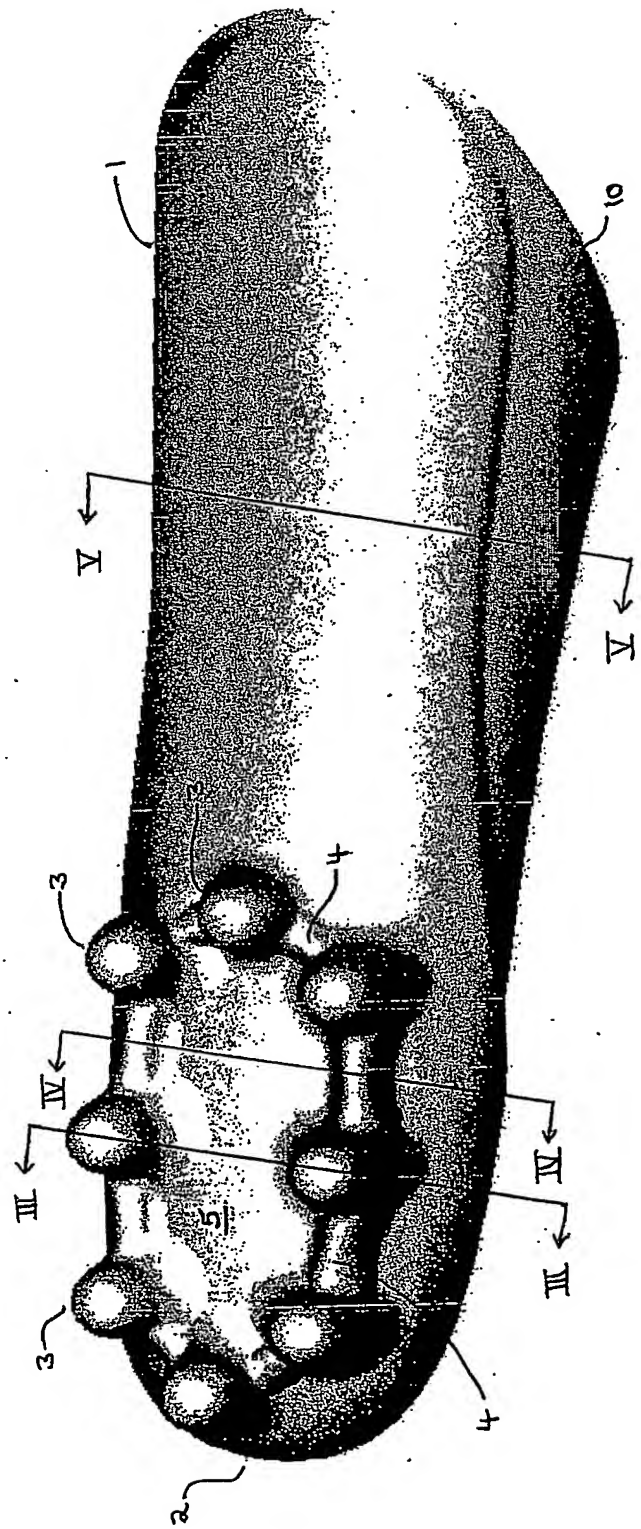

FIG. 1

Fig. 2

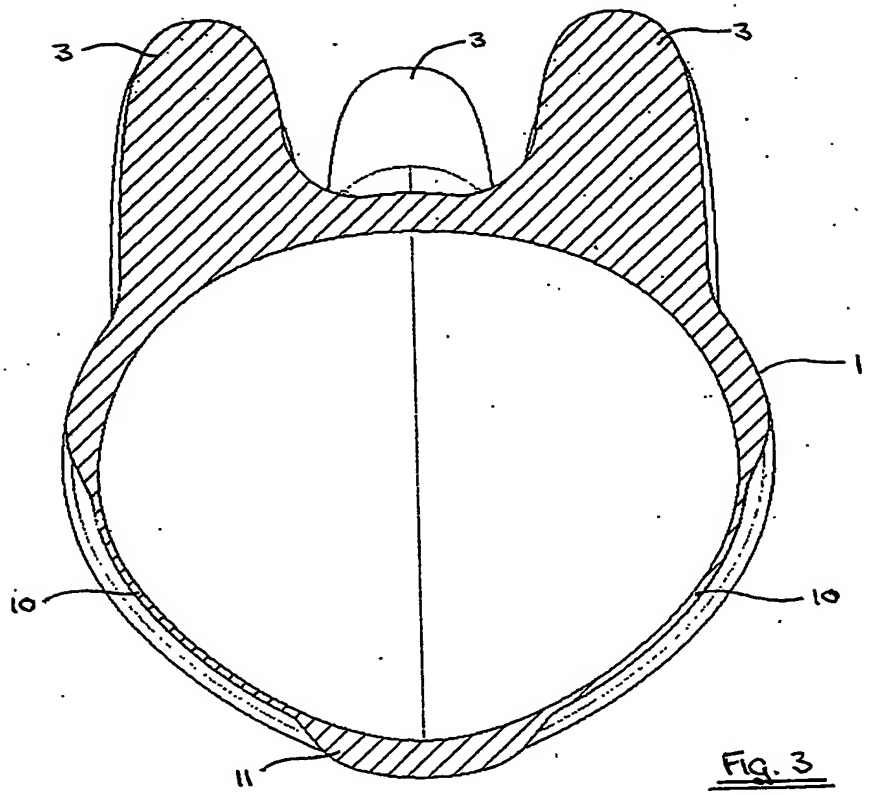

Fig. 3

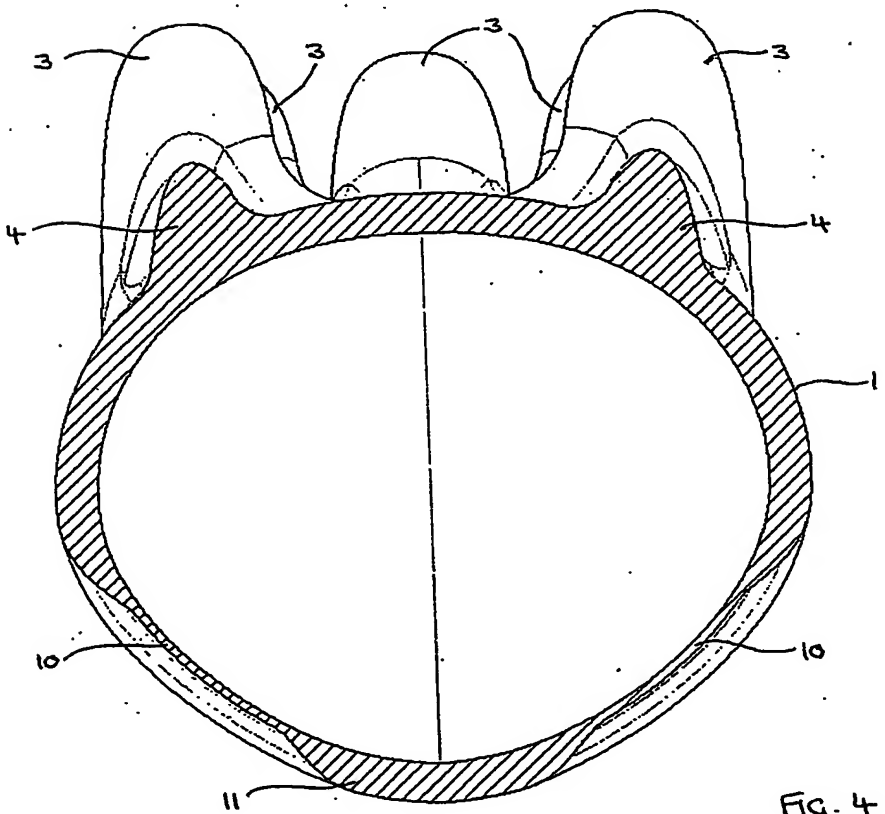

Fig. 4

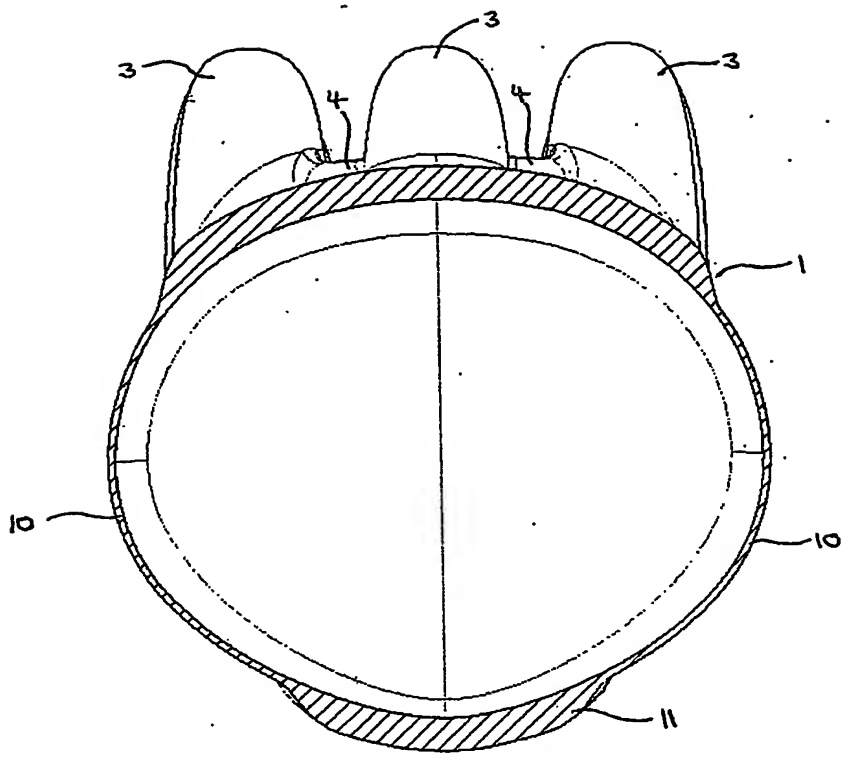

Fig. 5

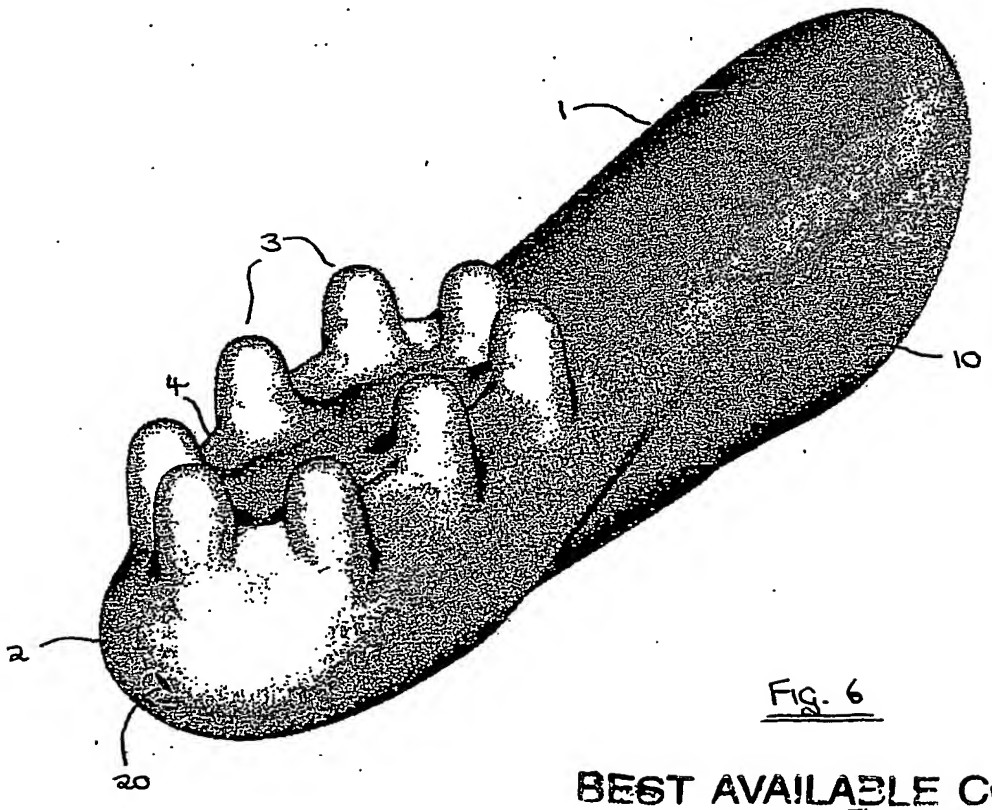

Fig. 6